Docket No. 2570-1-001N

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT :	Stamatatos et al.		
SERIAL NO. :	09/891,609	EXAMINER :	Jeffrey Parkin
FILED :	June 26, 2001	ART UNIT :	1648
FOR :	HIV-1 Vaccines and Screening Methods Therefor		

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Loretta Kavanagh
(Name of Person Depositing Mail)

Loretta Kavanagh 2/17/05
(Signature and Date)

INTERVIEW SUMMARY

MAIL STOP AMENDMENT
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Sir:

A Request for Continued Examination was filed for the above-noted application on August 23, 2004. A first Office Action was issued on November 17, 2004, and following receipt of this Office Action, Applicants' agent of record, Veronica Mallon, requested a telephonic interview with the Examiner. Such telephonic interview transpired on December 4, 2004.

During the interview, Dr. Mallon further clarified that the references forwarded in a Supplemental Information Disclosure Statement on March 8, 2004 demonstrate that the Stamatatos and Cheng-Mayer reference does not render the pending claim unpatentable under 35 U.S.C. 103(a). In particular, Dr. Mallon clarified that the various papers forwarded contained various HIV loop deletions, some of which overlapped with a

portion of the V2 loop deletion contained in the viral mutant claimed in the present application. More particularly, the discussion centered on a paper by Haigwood et al. (AIDS Research and Human Retroviruses, Vol. 6, No. 7, pp. 855-869, 1990) whereby the authors utilized a virus construct which contained both V1 (amino acids 131-154) and V2 (amino acids 156-198) loop deletions. This construct, upon injection into animals, was not able to induce a heterologous antibody response, thus teaching away from the present invention. Applicants, contrary to the attempts of Haigwood et al., were able to induce a cross-clade neutralizing antibody response with a viral mutant having a V2 loop deletion at amino acids 160-189.

The Examiner noted that the virus mutant of Haigwood et al. was not the same as that used in the instant invention, and therefore did not teach away from the invention. Dr. Mallon pointed out that while the construct of Haigwood et al. was not identical in that it contained both a V1 and V2 loop deletion, the areas deleted from the V2 loop should have exposed an even greater area such that heterologous antibodies should have been induced, but were not. The Examiner indicated that since the regions in the V2 loop of the Stamatatos viral mutant appear to be critical for inducing cross-clade neutralizing antibodies, Applicant should consider amending the claims to recite the particular regions in the construct where the deletions were made, eg. amino acids 160-189 of the V2 region, to distinguish over the prior art.

Additional points discussed included a statement made by the Examiner in the Office Action, alleging that the Stamatatos and Cheng-Mayer reference discloses that viral mutants having the V2 loop deletion were capable of inducing broadly neutralizing antibodies as evidenced by the patient data. Dr. Mallon clarified that this was not shown in the Stamatatos and Cheng-Mayer paper and more specifically, was not shown until the time of the present invention. The studies in the Stamatatos and Cheng-Mayer paper demonstrate that sera obtained from HIV patients was able to neutralize the viral mutant, which is not the same as showing that this particular HIV mutant strain could actively induce a cross-clade antibody response when administered to an animal as a vaccine.

Fees

It is believed that no fees are necessary in connection with this submission. However, if any fees are due, authorization is hereby given to charge Deposit Account No. 11-1153 for any underpayment.

CONCLUSION

Based on the foregoing discussion, Dr. Mallon noted that she would discuss this matter further with her client and would address the issues in a response to the Office Action if the client agreed to the amendments proposed by the Examiner.

Respectfully submitted,

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